510(k) Summary

JUL - 1 2008

Introduction

This summary is intended to comply with requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Applicant

H.C. Starck Ceramics GmbH & Co. KG
Lorenz-Hutschenreuther-Str. 81
95100 Selb, GERMANY
Tel: +49 92 878 07-0 / Fax: 92 878 07-477

510(k) Correspondent

Robert N. Clark, President and Senior Consultant
Medical Device Regulatory Advisors
13605 West 7th Ave., Golden, CO USA
Tel: 303-463-0900 / Fax: 303-558-3833

Date Prepared

April 28, 2008

Trade Name of Device

StarCeram

Common Name of Device

Powder, Porcelain

Classification Name

Porcelain powder for clinical use

510(k) Classification

Class II

Predicate Devices

K051462 DENTSPLY International Cercon Base

K062695 Sagemax Bioceramics, Inc. Sagemax Z-Blank

K072569 Metoxit CAM Blanks

Device Description and Intended Use

Dental blanks made of StarCeram® Z-Med or StarCeram® Z-Al-Med HD are dental materials (semifinished products) made of yttrium stabilized, presintered zirconium dioxide for milled production of crowns and bridge frameworks on commercial CAD/CAM systems or hand-operated copy-milling machines, with outstanding biocompatibility and high resistance against tension and pressure.

Dental Blanks made from StarCeram® Z-Med or StarCeram® Z-Al-Med HD are indicated for crowns, multi-unit bridges and inlay bridges. Applications include both anterior and posterior bridges.

Clinical and Non-Clinical Testing

H.C. Starck Ceramics GmbH & Co. KG did not conduct, nor rely upon, clinical tests to determine substantial equivalence. Non-clinical testing was performed in order to validate the design against the company's specified design requirements, and to assure conformance with the following voluntary design standards:

ANSI ADA Specifications No. 69:1999

ISO 6872:1995 + Amendment 1-1997

Risk Management

This device has been designed to either completely eliminate or mitigate known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program according to ISO 14971 "Medical devices - Application of risk management to medical devices"

Substantial Equivalence

H.C. Starck Ceramics GmbH & Co. KG believes that StarCeram is safe and effective when used as instructed by knowledgeable and trained personnel, and is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2008

H.C. Starck Ceramics GmbH & Co. KG
C/O Mr. Robert N. Clark
President and Senior Consultant
Medical Device Regulatory Advisors, Incorporated
13605 West 7th Avenue
Golden, Colorado 80401-4604

Re: K081263
Trade/Device Name: StarCeram®
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: April 28, 2008
Received: May 5, 2008

Dear Mr. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081263

Device Name: StarCeram

Indications for Use:

Dental Blanks made from StarCeram® Z-Med or StarCeram® Z-Al-Med HD are indicated for crowns, multi-unit bridges and inlay bridges. Applications include both anterior and posterior bridges.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kai Mulay for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081263